SEP 1 3 2000

K002383

9 510(k) Summary

Submitted By: Brenda Davis
Regulatory Affairs
COOK OB/GYN™
1100 West Morgan Street
Spencer, Indiana, 47460.
812 829-6500

August 3, 2000

Names of Device:

Trade Name:	Cook IVF Sperm Solutions
Common/Usual Name:	Sperm Processing Solutions
Classification Name:	Reproductive media and supplements 21 CFR §884.6180 (87MQL)

Predicate Device: 63 FR 48428, September 10, 1998

Device Description:
Cook IVF Sperm Solutions are aqueous solutions provided in glass vials with silicone rubber stoppers. The Cook IVF Sperm Buffer and Sperm Medium solutions will be available in 50 and 100 mL fill volumes, and the Cook IVF Sperm Gradient Kit will be available in 20 and 50 mL fill volumes.

Intended Use:
Cook IVF Sperm Solutions are intended for use during *in vitro* fertilization procedures to process sperm.

Substantial Equivalence:
The Cook IVF Sperm Solutions are comparable with respect to intended use to the published predicate device description and meet the requirements for 510(k) substantial equivalence.

Discussion of Tests and Test Results:
The Cook IVF Sperm Solutions were subjected to testing to assure satisfactory operating performance. The Cook IVF Sperm Solutions passed the requirements of all tests.

Conclusions Drawn from Tests:
This device is similar, with respect to intended use and technological characteristics, to the FDA published predicate device description.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 3 2000

Ms. Brenda Davis
Regulatory Affairs Technical Writer
Cook Ob/Gyn.
1100 W. Morgan Street
Spencer, Indiana 47460

Re: K002383
Cook IVF Sperm Buffer, Cook IVF Sperm Medium,
and Cook IVF Sperm Gradient Kit
Dated: August 3, 2000
Received: August 4, 2000
Regulatory Class: II
21 CFR 884.6180/Procode: 85 MQL

Dear Ms. Davis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K002383

Device Name: **Cook IVF Sperm Buffer**

Indications For Use: Cook IVF Sperm Buffer is intended for use during in vitro fertilization procedures to process sperm.

Device Name: **Cook IVF Sperm Medium**

Indications For Use: Cook IVF Sperm Medium is intended for use during in vitro fertilization procedures to process sperm.

Device Name: **Cook IVF Sperm Gradient Kit**

Indications For Use: Cook IVF Sperm Gradient Kit is intended for use during in vitro fertilization procedures to separate motile sperm from seminal plasma.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002383

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)